K120402

510(k) Summary
Crux Vena Cava Filter System
21 CFR 807.92

JUL 13 2012

Device Common Name:	Vena Cava Filter
Applicant / Manufacturer:	Crux Biomedical, Inc. 1455 Adams Drive, #1170 Menlo Park, CA USA 94025 Tel: 650-321-9903 Fax: 650-321-9904
Correspondent Contact Information:	Elisa Hebb Vice President, Clinical and Regulatory Affairs Crux Biomedical, Inc. 1455 Adams Drive, #1170 Menlo Park, CA 94025 Tel: 650-321-9903 Fax: 650-321-9904 Email: ehebb@cruxbiomedical.com
Device Classification Regulation & Name:	21 CFR 870.3375, Cardiovascular intravascular filters
Device Classification & Product Codes:	Class II, DTK
Panel:	Cardiovascular
Prior FDA Document Numbers:	G070035/S001 through G070035/S032
Device Proprietary Name:	Crux Vena Cava Filter System
Basis of Submission:	New Device
Kit Description: **Number of Devices in Submission**	Crux Vena Cava Filter System consists of: • Crux Vena Cava Filter • Crux Delivery Catheter • 7014 – Crux Vena Cava Filter System – Femoral • 7015 – Crux Vena Cava Filter System - Jugular

Intended Use

The Crux VCF System is indicated for the prevention of recurrent pulmonary embolism via percutaneous placement in the inferior vena cava (IVC) in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated
- Failure of anticoagulant therapy in thromboembolic diseases

- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated

The Crux VCF may be removed according to the instructions contained in the Instructions for Use section "Optional Retrieval of the Crux VCF" in patients who no longer require a vena cava filter. Retrieval of the filter can be performed by femoral or jugular approach.

Device Description – Crux Vena Cava Filter (VCF) System

The Crux VCF System is an endovascular medical device used in the prevention of recurrent pulmonary embolism (PE). The system consists of a self-expanding Nitinol filter delivered from a single-use, disposable 9Fr catheter, which can be used percutaneously to deploy the filter. The filter wireforms are composed of two opposing self-expanding Nitinol spiral elements connected at each end with Nitinol crimps. One end of each wireform is formed into a sinusoidal shaped retrieval tail to aid in retrieval of the filter using a snare. Each retrieval tail has an atraumatic plasma ball and a radiopaque tantalum marker band to facilitate visualization. There are five tissue anchors attached to the wireforms elements with Nitinol tubing. The filter is designed to treat IVC diameters of 17 to 28mm.

The delivery catheter for the Crux VCF is a disposable, 9Fr introducer-sheath-compatible, single-use delivery catheter. The filter is provided loaded in the Crux VCF System for jugular or femoral approach delivery. The delivery catheter is an over-the-wire system, 0.035" guidewire-compatible, and consists of a polycarbonate inner shaft and a nylon outer shaft. The inner shaft consists of the guidewire lumen and a flexible, radiopaque tracking tip. The outer shaft has a radiopaque distal marker band, a Touhy-Borst hemostasis valve and a one-way checkvalve for flushing.

The filter can be retrieved with commercially available snares and sheaths via either the jugular or femoral approach.

Predicate Device Information

Predicate Device:	Option Vena Cava Filter
510(k) Numbers:	K081410

Device Manufacturer:	Rex Medical 100 East Hector St, Suite 245 Conshocken, PA 19428
Device Common Name:	Cardiovascular Filter
Device Classification Name:	21 CFR 870.3375, Cardiovascular intravascular filters
Device Classification & Codes:	Class II, DTK

Comparison to Predicate Device

Both the Crux VCF System and predicate device share similar designs, mode of operation and materials. Both filters are delivered to the vena cava via transcatheter approach. When deployed, the nitinol material utilized in both the predicate and subject devices allows for self-centering of the filter. Both filters are designed with anchors to secure the filter to vessel wall and both filters can be safely retrieved via catheterization.

The primary differences between the predicate and subject devices are the filter geometry and the addition of ePTFE filter web incorporated in the Crux VCF design. Based on the design verification and validation results, the variation in geometry and addition of the ePTFE filter web do not have an adverse impact on the safety and effectiveness of the VCF when compared to the predicate device.

As demonstrated in the results of the clinical trial, these differences in design do not adversely affect the clinical outcomes when compared to the predicate device and the devices are substantially equivalent.

Other areas of substantial equivalence with predicate device:

- Intended Use
- Indications for Use
- Target Patient Population
- Mode of Operations

Summary of Supporting Data

Performance testing was conducted to establish substantial equivalence to the predicate device as outlined below:

In vitro testing

- Biocompatibility
- Shipping and Packaging

Dimensional and Visual Inspection
Deployment
Retrievability
Trackability
Deployment
Radial Force
Bond and Torque Strength
MRI Compatibility
Clot Trapping
Fatigue
Corrosion

In vivo testing (Pre-clinical)

Deployment
Retrieval
Positional Stability
IVC histopathology

Clinical Testing Summary:

A clinical trial was conducted under an approved IDE and IRB protocol to further establish the safety, effectiveness and substantial equivalence to the predicate device. One hundred and twenty-five (125) subjects with a temporary or permanent risk of recurrent pulmonary embolism were enrolled into a prospective, single arm, multinational clinical trial. Subjects were followed for 180 days or 30 days after filter retrieval. The primary endpoint of clinical success is defined as technical success of deployment and freedom from PE, filter migration, and device related adverse events requiring intervention. Secondary endpoints include retrieval success, filter migration, IVCF thrombosis, and device integrity.

The technical success rate was 123/125 (98%). There were 3 cases of recurrent PE (2.4%) and no cases of embolization, migration or fracture. There were 8 cases of asymptomatic, new inferior vena cava (IVC) thrombus including 5 observed at retrieval evaluation. Clinical Success was 96% (91.8% lower one-sided 95% CL exceeding the 80). Retrieval success was 53/54 (98%) at a mean of 83 ± 57 days (range 7 to 190) with 1 radiographic anomaly observed with no clinical sequelae.

The clinical trial demonstrated the safe deployment, implant and retrieval of the filter. Technical and retrieval success are high, with a low rate of device related complications.

Conclusion:

Bench test, animal test and the clinical trial results demonstrate that the device meets the established success criteria and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Crux Biomedical, Inc.
c/o Ms. Elisa Hebb
Vice President, Clinical and Regulatory Affairs
1455 Adams Drive, # 1170
Menlo Park, CA 94025

JUL 13 2012

Re: K120402
Trade/Device Name: Crux Vena Cava Filter System
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular intravascular filter
Regulatory Class: Class II
Product Code: DTK
Dated: July 9, 2012
Received: July 10, 2012

Dear Ms. Hebb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. A. Hillebrenner

for Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: This application K120402

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Indications For Use:

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Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices

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